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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,572	02/11/2004	David Burton	24,577-45CIP	6003
7590 John F. Klos, Esq. Fulbright & Jaworski L.L.P. 80 South Eighth Street, Suite 2100 Minneapolis, MN 55402-2112			EXAMINER ALI, SHUMAYA B	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 04/03/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,572

Applicant(s)

BURTON, DAVID

Examiner

SHUMAYA B. ALI

Art Unit

3771

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. In response to the office action mailed on 9/19/07, Applicant amended claims 1, 8, 14, 17-19, 21, 23-30, and cancelled claims 12, 13, 31, and 32. Currently, claims 1-11, 14-30 are pending in the instant application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the processor must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-11, 14, 15, 14-20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US 5,353,788 in view of Burton US 6,397,845 B1.

As to claim 8, Miles discloses a gas delivery system comprising a mask (see labeled fig.2, attachment below) having an EEG sensor (col.4, lines 55-60) connected (col.4, lines 43-45) thereto; a gas delivery device (fig.2,1) having an adjustable gas delivery setting (gas delivery adjustment is possible via 12). Miles discloses the EEG sensor activity is measured during sleep stage (see col.3 line 67), however, is silent on his processor (fig.2, 12) in communication with the gas delivery device and the sensor, the processor is adapted to determine the existence of a sleep and to adjust the gas delivery setting based on sleep stage of the patient. However, Burton in an apparatus for gas delivery teaches his system monitor physiological parameters (i.e. EEG, see col.6 lines 60-68) and has a processing means (12) that controls and adjusts positive air pressure based on a determined sleep stage of the patient (see col.3 lines 30-37). Therefore, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles's processor so that processor can operate and respond to EEG signal during patient's sleep stage as taught by Burton.

As to claim 9, Miles discloses sensor for abdominal and leg movement (see col.5, lines 55-57), thus discloses EMG sensor.

As to claim 10, Miles discloses sensor that detects heart rate (col.3, lines 55-60), thus discloses ECG sensor.

As to claim 11, Miles discloses blood oxygen saturation sensor, thus discloses SPO2 sensor (see col.4, lines 55-60).

As to claim 14, Miles discloses a gas delivery system comprising a mask (see labeled fig.2 attachment below) having at least one EEG sensor (col.4, lines 55-60) connected thereto, a gas delivery device (fig.2,1) having an adjustable gas delivery setting (delivery is adjusted via a processor 12); a processor (fig.2, 12) in communication with the gas delivery device and the EEG sensor, the processor adapted to determine a patient's sleep stage and to adjust the gas delivery setting based thereon as applied for claim 8.

As to claim 15, Miles discloses blood oxygen saturation sensor, thus discloses SPO2 sensor (see col.4, lines 55-60), and further discloses a sensor to detect heart rate, thus discloses an ECG sensor (col.3, lines 55-60) connected to the mask (col.4, lines 34-37). Miles further teaches a processor (fig.2, 12, col.5, lines 26 and 27, lines 48-50, and col.6, lines 17-24) that can inherently derive a PTT value from an output of each sensor.

As to claim 24, Miles discloses an apparatus comprising a mask (see fig.2 attachment below) having a body position sensor (see col.4, lines 55-60) attached thereto (see col.4, lines

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33-37), a processor (fig.2, 12) in communication with the body position sensor and adapted to a determine body position form the body position sensor's output (see col.5 lines 20-68, and col.6, lines 1-30).

As to claim 25, Miles discloses movement sensor (col.4, lines 55-60) attached to the mask (col.4, lines 33-37) and in communication with the processor and wherein the processor is adapted to determine movement from an output of the movement sensor (see col.5, lines 20-68, and col.6, lines 1-30).

As to claim 17-20, Miles discloses a mask with various physiological sensors (col.4, lines 55-60) that can determine arousal, a CPAP equipment that provides a supply of gas to a patient (col.3, lines 65-68), a processor that communicates with those sensors (col.5, lines 25-68, and col.6, lines 1-30), which is capable of calculating pulse transit time and cortical and subcortical signal. Burton as applied for claim 8 teaches the processor determining and adjusting air pressure at determined sleep stage of the patient. Although Miles/Burton lacks the detailed method steps cited for claims 17-20, however, Miles/Burton teaches a device that is fully capable of providing the method steps as claimed. Therefore, the method steps for claims 17-20 would have been obvious result of using the device of Miles in view of Burton.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles and Burton as applied to claim 18 above, and further in view of Cui et al. US 5,584,296.

As to claim 21, Miles/Burton lacks claimed method steps. However, Cui teaches attaching a light source (fig.2, 36) and a light sensor (fig.2, 32) on a mask so that the light source

and light sensor are positioned to contact a person's forehead (see fig.1), illuminating the light source (col.2, lines 63-66); detecting light from the light source (via 32, 34) as it deflects from the person's skull; and converting (via 20, see fi.1) the detected light into an analog signal. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate method steps as claimed to the method of Miles/Burton for the purposes of reading sensor detection as taught by Cui.

As to claim 22, Burton teaches means for filtering signal (see col.4 lines 32-36).

Although Burton does not specifically state "high pass filtering", filtering analog sound using high/low pass filtering is a conventional method of filtering sounds.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US 5,353,788 in view of Genger et al. WO00/66209 (note: US 7,054,680 B1 is the rejection for translation purpose) and further in view of Burton US 6,397,845 B1.

As to claims 1, Miles discloses a mask assembly (3, 26) comprising a body (see fig.2, attachment below) having an internal surface (see fig.2, mask inherently have external and internal surface), an external surface (see fig.2, attachment below), and a perimeter surface (see fig.2 attachment below); and a forehead support (see fig.2 attachment below) connected to the body. Miles further discloses EEG sensor (see col.4, lines 55-59). Miles however lacks the forehead support having an EEG sensor (see col.4, lines 44-45; lines 55-59). However, Genger teaches a forehead support bar with sensor that reads brain activity (see fig.1, 9/10/11; see col.1, lines 20-22). Applicant's EEG sensor also detects brain activity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to

change the location of the EEG sensor for the purposes of detecting electrical potential on a patient with an electrode device which can be applied in the forehead as taught by Genger (see col.1, lines 45-50). Miles discloses a processor (25) and a gas delivery device (1). Miles however lacks the process determine patient's sleep stage and provide gas delivery based on determination from patients sleep stage. However, Burton teaches processor monitoring and proving gas delivery based on determination of patient's sleep stage as applied for calim 8.

7. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles and Burton as applied to claim 14 above, and further in view of Genger et al. WO 00/66209 (note: US 7,054,680 B1 is the rejection for translation purpose)

As to claim 27, Miles discloses a mask, forehead support with sensors applied for claim 1.

As to claim 28, Genger teaches forehead support pad (see fig.4, 8).

As to claim 29, Miles discloses a movement sensor (see col.4, lines 55-60).

8. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Genger, and Burton as applied to claim 1 above, and further in view of Kwok US Patent No. 6532961 B1

As to claims 2 and 3, Miles lacks padding and forehead support bar, however mask with such features are well known in the art. Kwok teaches padding (25) and forehead support bar (12). Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to modify Miles for the purposes of providing cushioning to the forehead using

padding and enhance strap attachment with comfort around the forehead as taught by Kwok (see Kwok col.4 lines 15-20, and 40-45).

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Genger, Burton, and Kwok as applied to claim 1 above, and further in view of Cui et al. US Patent No. 5,584,296.

As to claim 4, Miles lacks an SPO2 sensor is located on the forehead support bar. However, Cui teaches that the blood oxygen saturation sensor, hence SPO2 can be located human skull ("forehead") for monitoring internal brain tissue (see col.1, lines 66-68 and lines 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention is made to locate SPO2 sensor on the forehead support bar of Genger for the purposes of monitoring internal brain tissue as taught by Cui.

10. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Genger, Burton, Kwok, Cui as applied to claim 4 above, and further in view of Duroousseau US Patent No. 6,708,051 B1.

As to claim 5, Miles as modified lacks sensor includes a pad comprised of a conductive carbonized rubber material. However, Duroousseau teaches carbonized plastic or conductive plastic electrodes in connection with carbon lead wires can be used to limit the susceptibility of his system to physiological and electronically induced contamination (see col.2, lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art the time the invention was made to modify Miles in order to provide a pad with conductive carbonized rubber material

for the purposes of limiting the susceptibility of the sensor to physiological and electronically induced contamination as taught by Dourousseau.

As to claim 7, Dourousseau teaches a portion of the conductive material is adapted to measure EOG (col.1, lines 20-25).

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Genger, and Burton as applied to claim 1 above, and further in view of Brown US 6,000,395.

As to claim 6, Miles discloses a strap extending from the mask (see labeled fig.2 attachment below) and physiological sensors (see col.4. lines 33-35, lines 44-45; lines 55-59; col.5 lines 615, and col.7 lines 37-51), however, lacks said sensor is located on the strap. However, Brown teaches physiological sensors can be located on the strap (see fig.1f, 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to change the location of the physiological sensor because it is known in the art as taught by Brown.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Burton as applied to claim 14 above, and further in view of Brown US 6,000,395.

As to claim 16, Miles discloses sensors that detect abdominal and leg movements (see col.4, lines 55-60), thus teaches EMG sensor that is located on mask (see col.4, lines 34-37). Miles however lacks sensors located on strap. However, Brown teaches physiological sensors

can be located on the strap (see fig.1f, 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to change the location of the physiological sensor because it is known in the art as taught by Brown.

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Burton as applied to claim 18 above, and further in view of Brown US 6,000,395.

As to claim 23, Miles discloses a method of detecting oral or nasal breathing during nasal ventilation, the method comprising providing a mask adapted to form a seal between a patient's nose and mouth (seal is provided by straps, see fig.2 attachment below), the mask inherently having an interior surface and an exterior surface, the mask also having a first thermal sensor (see col.4, lines 55-60) on the interior surface (see col.4, lines 33-37) and a second thermal sensor (see col.4, lines 33-37). Miles however lacks the thermal sensor is located on the exterior surface to be adjacent the patient's mouth. However Brown teaches thermal sensor can be located on strap (see fig.1f, 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to change the location of the physiological sensor because it is known in the art as taught by Brown. Miles further discloses detecting a temperature change (via processor 12, see fig.2) in the first or second thermal sensor (see col.5, lines 20-68, and col.6, lines 1-30). Thus, it would have been obvious to obtain the method steps of claim 23 using the device of Miles as modified by Burton and Brown.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Burton as applied to claim 17 above, and further in view of Tripp, Jr. US H1039.

As to claim 26, Miles/Burton lacks claimed method steps. However, Tripp teaches providing a perimeter surface of the mask with a plurality of thermally conductive surface distributed though out the perimeter surface (sensors 132, 133, 138, 140, 210, 212, 226, and 228). Tripp however is silent on method step of detecting a temperature change in any of the plurality of thermally conductive surface. However, Tripp teaches an electronic processing circuitry (see col.3, liens 6-9) which is considered to detect the temperature changes in any of the plurality of thermally conductive surface. Therefore, the method steps cited for claim 25 would have been obvious over using the apparatus of Tripp. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mils in order to provide claimed steps for the purposes of detecting leak as taught by Tripp (col.1, 46-53).

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Burton, Genger, as applied to claim 27 above, and further in view of Tripp, Jr. US H1039.

As to claim 30, Miles lacks a mask seal leakage detector. However, Tripp teaches perimeter surface of a mask is adapted to sense air leaks (see col.11, lines 46-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles in order to include a leakage detector for the purposes of detecting air passing between the mask and the external environment as taught by Tripp.

Response to Arguments

16. Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shumaya B. Ali /
Examiner, Art Unit 3771

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771